<u>REMARKS</u>

In the Office Action dated May 21, 208, the Examiner states that this application contains the following groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1, and therefore restriction is required under 35 U.S.C. §§121 and 372.

- Group I. Claims 1-2 and 4-12, drawn to a compound that modulates G-CSF-induced cellular responses via a SOCS molecule wherein the compound up-regulates SOCS-3 level.
- Group II. Claims 1 and 3-12, drawn to a compound that modulates G-CSF induced cellular responses via a SOCS molecule wherein the compound down-regulates SOCS-3 level.
- Group III. Claims 13-15, drawn to a method for modulating G-CSF induced cellular responses via a SOCS molecule comprising administering a compound that inhibits SOCS-3 level.
- Group IV. Claims 13-15, drawn to a method for modulation G-CSF-induced cellular responses via a SOCS molecule comprising administering a compound that elevates SOCS-3 level.
- Group V. Claims 16-17, drawn to animal model useful for screening for G-CSF modulating compounds.

In order to be fully responsive to the Examiner's requirements for restriction,

Applicants provisionally elect, with traverse, to prosecute the subject matter of Group IV, claims 13-15, drawn to a method for modulation G-CSF-induced cellular responses via a SOCS molecule comprising administering a compound that elevates SOCS-3 level. However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

Applicants respectfully submit that a requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R.

§1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added.)

According to the Examiner, the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The inventions of Groups I-V are found to have no special technical feature that defines a contribution over the prior art of Hortner et al. The first claimed invention in the instant application is a compound that modulates G-CSF-induced cellular responses via a SOCS molecule. Hortner et al. teach that a compound comprising human recombinant G-CSF up-regulates SOCS-3 level in cells and modulates G-CSFR-mediated signal transduction activity. Therefore, Applicant's inventions claimed in the instant application do not contribute a special technical feature when viewed over the prior art. Accordingly, the inventions of Groups I-V do not have a single inventive concept and lack unity of invention. Therefore restriction for examination purposes as indicated is proper.

Applicants respectfully submit that unity of invention is the issue at hand. The Examiner should not rely on an evaluation regarding novelty and/or inventive step of the present invention over certain prior art in order to determine whether the requirement of unity of invention is satisfied under PCT Rule 13.1. Applicants should be given the opportunity to argue

on the merits during prosecution whether the claims involve novelty and/or inventive step.

Restriction of the claims at this stage would deny Applicants such an opportunity.

Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined four groups, one from the other, as presented by the Examiner.

Accordingly, it is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the pending claims.

Respectfully submitted,

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